American Red Cross

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March 23, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods [DRAFT GUIDANCE: July 1998 (Docket Number 98D-0545).]

Dear Docket Officer:

The purpose of this letter is to provide comments on the Food and Drug Administration's (FDA) proposed guidance regarding double red cell apheresis procedures. The American Red Cross (Red Cross), through its Blood Services regions, supplies approximately 45% of the nation's blood transfusion needs. Thus, Red Cross maintains a strong interest in exploring new technology that may improve the safety or availability of the blood supply.

In July of 1998, the FDA published proposed double red cell apheresis procedures in an FDA Guidance for Industry Document entitled "Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods." At that time, Red Cross was not actively pursuing the use of this technology. However, since the publication of the proposed guidance, Red Cross has evaluated the Haemonetics MCS+ prior to the initiation of a pilot trial (FDA/CBER will shortly receive a notification of this pilot under separate cover). Thus, we are now more familiar with this technology and wish to provide public comments based on this evaluation.

As you are aware, donors of blood and blood products are subject to extensive pre-donation screening and those with disease risk factors are deferred. In addition, each unit from an accepted donor is subject to extensive testing for the presence of transmissible disease viruses. No blood product is distributed for transfusion until all screening tests are satisfactory. Thus, Red Cross agrees with the FDA's guidance that

> Blood establishments that intend to use FDA cleared devices to manufacture...two (2) units of Red Blood Cells, using automated methods should revise their SOPs ...include all the donor section criteria, record keeping, manufacturing procedures, product

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tracking, lot numbers of all disposables and fluids, and quality control acceptance criteria and test results.

However, we suggest several revisions to the document as follows:

Page 2; Section III A.2.a. Donation interval

The FDA Guidance Text reads as follows: *"Donors should not be eligible for whole blood donation or any other apheresis collection procedure until sixteen (16) weeks after a two (2) unit red cell blood cell donation"*

Red Cross suggests the following change: "Donors should not be eligible for whole blood donation or any other red blood cell collection procedure until sixteen (16) weeks after a two (2) unit red cell blood cell donation"

Justification: Apheresis procedures where additional red cells are not collected should have the same deferral period as apheresis procedures following whole blood donation.

Page 2, Section III.A.2.c. Donor Weight

The FDA Guidance Text states: *Donors should be weighed prior to each donation. Donors who are not weighed prior to each donation should not undergo the collection of two (2) units of red blood cells by apheresis.*

Red Cross suggests the following change: Delete this requirement.

Justification: We base many of our safety systems on donors honestly and accurately providing information to us during the health history process. There is no indication that donors would purposely report that they weigh more than they actually do.

Page 3: Section III.C.

The FDA Guidance Text reads as follows:

C. *Standard Operating Procedures and Record Keeping*
The blood establishment's SOP and records for blood collection should include the collection parameters set forth in the device operator's manual. These parameters should include, but not be limited to, the following:

1. *The pre-determined target volume of each unit of red blood cells to be removed from the donor as determined by the device operator's manual, based on the gender, height, weight, hematocrit and type of procedure.*

2. *The amount of normal saline solution, as recommended by the device manufacturer, to be administered to compensate for the volume of red blood cells lost through donation.*

3. *The hematocrit of the final red blood cell product as determined by the method described in the device operator's manual.*

4. *An absolute red blood cell volume of each product produced (Red Blood Cell product hematocrit X Red Blood Cell product volume).*

5. *A comparison of the calculated donation volume and the pre-determined target volume as determined by the donor's gender and hematocrit.*

Red Cross suggests changing the text of Section III.C. to read as follows:

C. Standard Operating Procedures and Record Keeping

The blood establishment's SOP and records for blood collection should include the collection parameters set forth in the device operator's manual.

1. These parameters should include, but not be limited to, the following:

   a. The pre-determined target volume of each unit of red blood cells to be removed from the donor as determined by the device operator's manual, based on the gender, height, weight, hematocrit and type of procedure.

   b. The amount of normal saline solution, as recommended by the device manufacturer, to be administered to compensate for the volume of red blood cells lost through donation.

2. In each month that 2 unit red blood cell apheresis is performed, the final red cell products from four (4) procedures shall be examined by the following:

a. The hematocrit of the final red blood cell product as determined by the method described in the device operator's manual.

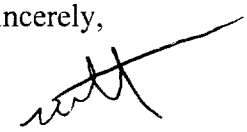
b. An absolute red blood cell volume of each product produced. (Red Blood Cell product hematocrit X Red Blood Cell product volume).

c. A comparison of the calculated donation volume and the pre-determined target volume as determined by the donor's gender and hematocrit.

Justification: The data developed and submitted to the FDA in support of the 510(k) demonstrated that the Haemonetics MCS+ produces a more consistent volume red cell product than a red cell product produced via whole blood collection. In addition, all manufacturers will have to validate the process prior to implementation in their facility. Finally, blood collection using the Haemonetics MCS+ is operated as a validated process monitored by periodic product quality control sampling so that performing product quality control examinations on every red cell product produced is unnecessary.

Red Cross appreciates the opportunity to provide comments on the guidance. If you have any questions, please contact Bill Kline, Director, Business Operations at 313-494-3422.

Sincerely,



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